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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,837	10/23/2003	Edward A. Byrd	MRIN-010	1014

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EXAMINER

VU, JAKE MINH

. ART UNIT	PAPER NUMBER
	1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)
	10/693,837	BYRD, EDWARD A.
	Examiner	Art Unit
	Jake M. Vu	1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 October 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-31 is/are pending in the application.
 - 4a) Of the above claim(s) 19-31 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's Information Disclosure Statements filed on 03/13/2005 and 08/20/2004; and Restriction Requirement Response filed on 10/25/2006. Claims 1-31 are pending in the instant application. Claims 19-31 are withdrawn from consideration.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-18) in the reply filed on 10/25/2006 is acknowledged. The traversal is on the ground(s) that it would not be unduly burdensome to perform the search on all of the claims together. This is not found persuasive because searching all of the claims would require searching in numerous different classes and subclasses, as well as a different searching focus depending on whether the product or method of using are being searched. Thus, the search would pose an undue burden on the Office.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent No. 7,118,762; 6,572,888; 6,197,340; and 6,191,162 in view of FISCHER (US 5,599,835). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patents recite an oral dosage formulation comprising of: a therapeutically effective amount of lipoic acid and an excipient material (see US 6,572,888 at claim 1), wherein the lipoic acid is present as a racemic mixture (see claim 7) or the lipoic acid is present as substantially pure R-(+) enantiomer (see claim 8); and a diabetic drug, such as metformin (see claim 16).

The '888 patent does not teach adding thiamine.

FISCHER disclosed treating diabetes mellitus by administering a composition comprised of lipoic acid and thiamine (see claim 1).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate thiamine into the '888 patent. The person of ordinary skill in the art would have been motivated to make that modification and reasonably

would have expected success because the patents dealt with the same subject matter of treating diabetic patients using lipoic acid.

Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over copending Application No. 11/199,919; 10/947,054; and 11/382,414. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending applications recite an oral dosage formulation comprising: lipoic acid and thiamine (see 10/947054, claim 1), wherein the lipoic acid comprises a racemic mixture of enantiomer (see claim 2) or the lipoic acid is present as substantially pure R-(+) enantiomer (see claim 13). The oral dosage formula may further comprise metformin (see claim 11). The only difference between the instant claims and the copending claims is that two other active agents, such as alpha-ketoglutarate and/or creatine may optionally be added to the oral formulation. Since the instant claims uses open language such as "comprising", these other active ingredients may be included.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by WEISCHER et al (US 5,569,670).

Applicant's claims are directed to an oral dosage formulation comprising of: lipoic acid; thiamine; and an excipient, wherein the lipoic acid comprises a racemic mixture of enantiomers or substantially pure R-(+) enantiomer of lipoic acid.

WEISCHER teaches an oral dosage formulation comprised of: lipoic acid (see abstract); thiamine, which is vitamin A (see abstract and col. 7, Table 1); and an excipient, such as microcrystalline cellulose (see col. 17, line 66 and col. 14, line 46 – col. 15, line 60), wherein the lipoic acid comprises a racemic mixture of enantiomers (see col. 4, line 5-6) or substantially pure R-(+) enantiomer of lipoic acid (see col. 2, line 43-45).

Note, the "capable of" limitations of release rate, such as first quick release rate and controlled rate, and therapeutic level are inherent to the prior art compositions, because the prior art has exactly the same ingredients as Applicant, namely lipoic acid, thiamine and an excipient material.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WEISCHER et al (cited supra) in view of MOECKEL et al (US 5,955,106).

As discussed above, WEISCHER teaches an oral dosage formulation comprised of: lipoic acid (see abstract); thiamine, which is vitamin A (see abstract and col. 7, Table 1); and an excipient, such as microcrystalline cellulose (see col. 17, line 66 and col. 14, line 46 – col. 15, line 60), wherein the lipoic acid comprises a racemic mixture of enantiomers (see col. 4, line 5-6) or substantially pure R-(+) enantiomer of lipoic acid (see col. 2, line 43-45). Additionally disclosure includes: using the composition to treat diabetes (see co. 2, line 43).

Note, the “capable of” limitations of release rate, such as first quick release rate and controlled rate, and therapeutic level are inherent to the prior art compositions, because the prior art has exactly the same ingredients as Applicant, namely lipoic acid, thiamine and an excipient material.

WEISCHER does not teach adding metformin to the composition.

MOECKEL disclosed that the prior art had known of controlled-release metformin was used for treating diabetes (see col. 1, line 1-26)

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate metformin into WEISCHER’s composition. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because the references dealt with the same subject matter of treating diabetes.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Telephonic Inquiries

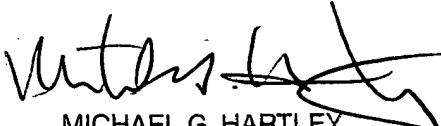
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jake M. Vu, PharmD, JD
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MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER